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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/070,758 | 03/12/2002 | Helmut Witteler | 50733 | 2769 |
| 26474 | 7590 | 01/04/2006 | EXAMINER | |
| NOVAK DRUCE DELUCA & QUIGG, LLP 1300 EYE STREET NW SUITE 400 EAST WASHINGTON, DC 20005 | | | FUBARA, BLESSING M | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1618 | | |

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/070,758 | WITTELER ET AL. | |
| | Examiner Blessing M. Fubara | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 August 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9 and 12 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Examiner acknowledges receipt of appellants' reply brief filed 08/25/05. Upon further consideration appellants' objection of the new rejection of claims 1-9 and 12 as being rendered obvious by Denzinger et al. (US 4,402,937), the finality of the final action is withdrawn and prosecution is reopened. The rejection below follows in response to appellants' reply brief of 08/25/05.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Denzinger et al. (US 4,402,937).

Denzinger discloses a process for preparing polyvinylpyrrolidone (PVP)-iodine by reacting the PVP with elemental iodine in the presence of formic acid, oxalic acid, or ammonium salt or amide of carbonic acid, formic acid or oxalic acid and the reaction is carried out in aqueous solution (abstract and column 3, lines 1 and 2). The preparation starts with an aqueous solution of PVP of from 10-60% (column 4, lines 33-37), the PVP has a K value of from 8-50 (column 3, lines 37-41). In example 1, iodine is in an amount of 6% based on the weight of PVP and an available amount of 4.1%. The available iodine in example 2 is 5.1% and 6.2% in example 3. The mixture of the PVP and iodine and formic acid is heated at 70 °C for 20 hours

(example 1), at 80 °C for 5 hours (example 2) and at 75 °C for 2 hours and a solid product is isolated from the aqueous solution by drying, spray drying or spray granulation (column 4, lines 53-56). See also claims 1-3. Instant claim 12 is a composition claim and future intended use is not critical in a composition claim. Formic acid is a reducing agent of the instant claims. The examples are exemplifications illustrating some aspects of the disclosed process and do not cover all possible combinations of the range of K-values of PVP solutions and the concentrations of the PVP-solution. Denzinger meets the limitations of the instant claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-9 and 12 are rejected in the alternative, under 35 U.S.C. 103(a) as obvious over Denzinger et al. (US 4,402,937).

The prior art reference is discussed above. The prior art reference discloses PVP K-values of from 8 to 50 and these values are within the range claimed by applicants. The prior art

discloses that the PVP-iodine solution prepared is about 50% higher in stability than that of the PVP-iodine solutions that have been previously prepared according to the previous state of the prior art (column 4, lines 44-48). The prior art fails to exemplify the claimed relationship. A review of the records does not establish relationship of the starting concentration of the PVP and reaction time for the preparation of the PVP-iodine on the stability of the PVP-iodine in aqueous solution. It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a PVP-iodine solution according to the process of Denzinger where the PVP-iodine solution is more stable than the PVP-iodine solution prepared as per the state of the prior art. One having ordinary skill in the art would have been motivated to optimize the starting concentration of the PVP by routine experimentation that would be expected to produce a PVP-iodine solution that is at least 50% higher in stability than that of the state of the prior art.

In response to appellants arguments (presented in the brief filed 08/12/2004) regarding the K values and PVP disclosed by Denzinger, it is noted that the prior art is clearly interested in stability and storage of the PVP-iodine solution and there is no degree of stability in the claims. It is obvious to adjust the concentration of the initial/startling concentration of the PVP to improve stability. Column 4, lines 44-48 of Denzinger discloses that "the stability of the novel PVP-iodine solutions is about 50% higher than that of solutions obtained by dissolving a PVP-iodine prepared according to German Published Application DAS No. 2,818,767," and this is an improvement over the prior art. No comparison with Denzinger is provided to demonstrate that applicants' PVP-iodine solution is more stable. No unexpected results are provided in the establishment of relationship between the PVP starting concentration and the K-values.

Applicants' improved stability is neither reflected in the scope of the claims nor evidenced in any of the data currently submitted.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Blessing Fubara
Patent Examiner
Tech. Center 1600

THURMAN K. PAGE, M.A., J.D.
SUPERVISORY PATENT EXAMINER

A handwritten signature of Thurman K. Page, consisting of stylized initials and a surname.